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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/530,335 | 06/13/2006 | Jan Wim Vrijbloed | 753-50 PCT/US | 4714 |
| 23869 7590 03/17/2009 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791 | | | | |
| EXAMINER | | | | |
| NIEBAUER, RONALD T | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1654 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 03/17/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,335

Applicant(s)

VRIJBLOED ET AL.

Examiner

RONALD T. NIEBAUER

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 1-45 are under consideration.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a three membered ring with nitrogen as in A1.

Group 2, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a four membered ring with nitrogen as in A2-A4, A76.

Group 3, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a five membered ring with nitrogen as in A5-A11, A79, A82-A83.

Group 4, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a five membered ring with nitrogen attached to a six membered ring as in A12-A14, A89, A92, A97.

Group 5, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a six membered ring with nitrogen as in A15-A18, A20-A28, A89.

Group 6, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include two or more six membered rings as in A19, A29-A37, A100-101, 104.

Group 7, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a seven membered ring with nitrogen as in A38-A57.

Group 8, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a seven membered ring with nitrogen attached to at least one six membered ring as in A58-A69.

Group 9, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a linear residues as in A70-A72.

Group 10, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a three membered ring with no nitrogen in the ring as in A73.

Group 11, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a four membered ring with no nitrogen in the ring as in A74-A75.

Group 12, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a five membered ring with no nitrogen in the ring as in A77-A78, A80-A81.

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Group 13, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a five membered ring with no nitrogen in the ring and another six membered ring as in A84-A86.

Group 14, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a six membered ring with no nitrogen in the ring as in A87-A88,A90-91,A93-96.

Group 15, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae a1 or a2 and include a six membered ring with no nitrogen in the ring and another six membered ring as in A98-A99,A102-103.

Group 16, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae b1,b2,c1,c2,c3,e4,g,m, or p.

Group 17, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae c1,c2, or c3.

Group 18, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae d.

Group 19, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae f.

Group 20, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae h.

Group 21, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae i1,i2,i3 or i4.

Group 22, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae j.

Group 23, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae k.

Group 24, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae l.

Group 25, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae n.

Group 26, claim(s) 1-35 in part, drawn to compounds/compositions that include formulae o.

Group 27, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a three membered ring with nitrogen as in A1.

Group 28, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a four membered ring with nitrogen as in A2-A4,A76.

Group 29, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a five membered ring with nitrogen as in A5-A11,A79,A82-A83.

Group 30, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a five membered ring with nitrogen attached to a six membered ring as in A12-A14,A89,A92,A97.

Group 31, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a six membered ring with nitrogen as in A15-A18,A20-A28,A89.

Group 32, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include two or more six membered rings as in A19,A29-A37,A100-101,104.

Group 33, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a seven membered ring with nitrogen as in A38-A57.

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Group 34, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a seven membered ring with nitrogen attached to at least one six membered ring as in A58-A69.

Group 35, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a linear residues as in A70-A72.

Group 36, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a three membered ring with no nitrogen in the ring as in A73.

Group 37, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a four membered ring with no nitrogen in the ring as in A74-A75.

Group 38, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a five membered ring with no nitrogen in the ring as in A77-A78, A80-A81.

Group 39, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a five membered ring with no nitrogen in the ring and another six membered ring as in AA84-A86.

Group 40, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a six membered ring with no nitrogen in the ring as in A87-A88, A90-91, A93-96.

Group 41, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae a1 or a2 and include a six membered ring with no nitrogen in the ring and another six membered ring as in A98-A99, A102-103.

Group 42, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae b1, b2, e1, e2, e3, e4, g, m, or p.

Group 43, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae c1, c2, or c3.

Group 44, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae d.

Group 45, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae f.

Group 46, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae h.

Group 47, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae i1, i2, i3 or i4.

Group 48, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae j.

Group 49, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae k.

Group 50, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae l.

Group 51, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae n.

Group 52, claim(s) 36-37 in part, drawn to method of using as part of an administration compounds/compositions that include formulae o.

Group 53, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a three membered ring with nitrogen as in A1.

Group 54, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a four membered ring with nitrogen as in A2-A4,A76.

Group 55, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a five membered ring with nitrogen as in A5-A11,A79,A82-A83.

Group 56, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a five membered ring with nitrogen attached to a six membered ring as in A12-A14,A89,A92,A97.

Group 57, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a six membered ring with nitrogen as in A15-A18,A20-A28,A89.

Group 58, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include two or more six membered rings as in A19,A29-A37,A100-101,104.

Group 59, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a seven membered ring with nitrogen as in A38-A57.

Group 60, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a seven membered ring with nitrogen attached to at least one six membered ring as in A58-A69.

Group 61, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a linear residues as in A70-A72.

Group 62, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a three membered ring with no nitrogen in the ring as in A73.

Group 63, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a four membered ring with no nitrogen in the ring as in A74-A75.

Group 64, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a five membered ring with no nitrogen in the ring as in A77-A78,A80-A81.

Group 65, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a five membered ring with no nitrogen in the ring and another six membered ring as in A84-A86.

Group 66, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a six membered ring with no nitrogen in the ring as in A87-A88,A90-91,A93-96.

Group 67, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae a1 or a2 and include a six membered ring with no nitrogen in the ring and another six membered ring as in A98-A99,A102-103.

Group 68, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae b1,b2,c1,c2,c3,e4,g,m, or p.

Group 69, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae c1,c2, or c3.

Group 70, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae d.

Group 71, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae f.

Group 72, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae h.

Group 73, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae i1,i2,i3 or i4.

Group 74, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae j.

Group 75, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae k.

Group 76, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae l.

Group 77, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae n.

Group 78, claim(s) 38-45 in part, drawn to method of making compounds/compositions that include formulae o.

It is noted that claims 36-37 are drawn to a use claim (see MPEP 2173.05(q)). The claim is interpreted as being drawn to a method of using as part of an administration although applicant is invited to clarify the meaning of the claim.

The inventions listed as Groups 1-78 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Section 1850 of the MPEP states that the contribution over the prior art should be considered with respect to novelty and inventive step. Claim 1 is drawn to compounds of a general formula. Obrecht et al (WO 02/070547 as cited in

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IDS dated 7/5/05) teach peptidomimetics of formula Ia (abstract, claims 1-45). It is noted that a1,a2,b1,etc. and A1,A2,etc. of the claims of Obrecht are the same as the variables in the instant invention. Obrecht teach specific amino acids for positions P1-P12 (page 29,159,161,171,174). Obrecht teach the used of the compounds to inhibit the growth of microorganisms as antibacterials (abstract, page 1). The instant claims state a proviso that there be at least one residue of type I or of type K. Zuckermann et al (Polymer Preprints 35(2) 1994 pages 975-976) teach that the use of N-substituted glycine residues is known in the art (page 975). Zuckermann specifically teach that the N-substitution leads to protease stability and no chirality (Figure on page 975). Miller et al (Bioorganic and Medicinal Chemistry Letters v4 1994 pages 2657-2662) teach that N-substituted glycine peptides were essentially untouched by proteases while the L-amino acid peptides were readily cleaved (abstract). Miller teach that a variety of compounds could be substituted at the N position (see Figure 1). Goodson et al (Antimicrobial agents and chemotherapy v43 1999, pages 1429-1434) teach that N-substituted glycine peptides were found to have antibacterial properties (abstract page 1429). Taken together the prior art recognize the use of N-substituted glycine residues for improved stability and uses with antibacterial peptides. Since Obrecht teach specific peptides with Glycine residues (see page 61 SEQ ID NO:96-101 for example) one would be motivated to make an N-substitution at the glycine residue as in the type I or type K residues of the instant invention. Thus the technical features are not a contribution over the prior art and the claims lack unity.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For whichever group is elected, species election is necessary for:

Compound: a specific compound should be identified such that all variable groups are uniquely defined. For example, applicant could identify a specific sequence as set forth in one of the tables.

Further, if applicant elects any of Groups 27-52 a species election is necessary for:

Patient population: a specific patient population should be identified from those recited in claim 36-3. 7Applicant should identify a specific infection or disease (for example, a bacterial infection or cystic fibrosis).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

All claims are generic to at least one of the species.

There is an examination and search burden for the species due to their mutually exclusive characteristics. Each of the species are structurally distinct and one of skill in the art would not recognize that every alternative would behave in the same way. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654